



NUCLEAR REGULATORY COMMISSION

[Docket No. 03033009; EA-2021-157; NRC-2022-0179]

Confirmatory Order Modifying License of Cammenga and Associates, LLC

AGENCY: Nuclear Regulatory Commission.

ACTION: Confirmatory order; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing a Confirmatory Order to Cammenga and Associates, LLC, as a result of a successful alternative dispute resolution mediation session. The commitments outlined in the Confirmatory Order were made as a part of a settlement agreement concerning apparent violations by Cammenga and Associates regarding the distribution of products containing byproduct material (hydrogen-3) without the required licensing authorization.

DATES: The Confirmatory Order became effective on October 6, 2022.

ADDRESSES: Please refer to Docket ID **NRC-2022-0179** when contacting the NRC about the availability of information regarding this document. You may obtain publicly available information related to this document using any of the following methods:

- **Federal Rulemaking Website:** Go to <https://www.regulations.gov> and search for Docket ID **NRC-2022-0179**. Address questions about Docket IDs in Regulations.gov to Stacy Schumann; telephone: 301-415-0624; email: Stacy.Schumann@nrc.gov. For technical questions, contact the individual listed in the "For Further Information Contact" section of this document.

- **NRC's Agencywide Documents Access and Management System**

(ADAMS): You may obtain publicly available documents online in the ADAMS Public Documents collection at <https://www.nrc.gov/reading-rm/adams.html>. To begin the search, select "Begin Web-based ADAMS Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by email to PDR.Resource@nrc.gov. The Confirmatory Order modifying license of Cammenga and Associates, LLC. is available in ADAMS under

Accession No. ML22278A182.

- **NRC's PDR:** You may examine and purchase copies of public documents, by appointment, at the NRC's PDR, Room P1 B35, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. To make an appointment to visit the PDR, please send an email to PDR.Resource@nrc.gov or call 1-800-397-4209 or 301-415-4737, between 8:00 a.m. and 4:00 p.m. Eastern Time (ET), Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Carmen Rivera-Diaz, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone: 301-415-0296, email: Carmen.RiveraDiaz@nrc.gov

SUPPLEMENTARY INFORMATION: The text of the order is attached.

Dated: October 14, 2022.

For the Nuclear Regulatory Commission.

Dori Willis,
Acting Director,
Office of Enforcement.

Attachment – Confirmatory Order Modifying License of Cammenga and Associates, LLC

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

In the Matter of)	Docket Nos. 03038679
Cammenga and Associates, Inc.)	License Nos. 21-26460-03E
Dearborn, Michigan)	SSD Registration No.: NR-0210-D-
101-E)	EA-21-157

CONFIRMATORY ORDER MODIFYING LICENSE
EFFECTIVE UPON ISSUANCE

I

Cammenga and Associates, LLC, (Cammenga or Licensee) is the holder of Materials License No. 21-26460-03E and Sealed Source and Device Registration (SSD) Certificate No. NR-0210-D-101-E issued by the U.S. Nuclear Regulatory Commission (NRC) pursuant to Part 30 and 32 of Title 10 of the *Code of Federal Regulations* (10 CFR). The license authorizes Cammenga to distribute products containing byproduct material (tritium, hydrogen-3) to persons exempt from the regulations. For the products authorized under License No. 21-26460-03E, an SSD is required and is captured as a License Condition in the license. The SSD identifies the models that are authorized for distribution under the license.

This Confirmatory Order is the result of an agreement reached during an alternative dispute resolution (ADR) mediation session conducted on June 28, 2022.

II

The NRC conducted investigations in 2021 (OI Case No. 3-2021-008) related to apparent violations by Cammenga regarding the distribution of products containing byproduct material (hydrogen-3) without the required licensing authorization.

On March 17, 2022, the NRC issued a letter to Cammenga that detailed the results of the investigation and outlined two apparent violations. The first apparent violation involved Cammenga's failure to limit its distribution of self-luminous products to the products authorized in its NRC License No. 21-26460-03E. The product was listed on a redistributor's website as the Tritium Pry Bar. Specifically, between late 2020 and January 27, 2021, the licensee distributed to an unlicensed entity at least 25 Tritium Pry Bars that were not included in the products authorized in NRC License No. 21-26460-03E, in accordance with NRC SSD registration certificate No. NR-0210-D-101-E. The second apparent violation involved Cammenga's failure to limit its distribution of self-luminous products to the products authorized in its NRC License No. 21-26460-03E. The product was listed on a redistributor's website as the Tritium Glow Fob. Specifically, between late 2020 and January 27, 2021, the licensee distributed to an unlicensed entity at least 10 Tritium Glow Fobs that were not included in the products authorized in NRC License No. 21-26460-03E, in accordance with NRC SSD registration certificate No. NR-0210-D-101-E.

The failure to conduct activities in accordance with a license is significant because it resulted in the NRC not being able to conduct its regulatory responsibilities to ensure that the products were safe for distribution to members of the public, and it inhibited the process of regulatory oversight.

The NRC determined that regarding the first violation identified in the March 17, 2022, letter, Cammenga's actions were willful. Specifically, Cammenga distributed 25 products containing tritium, identified in the March 17, 2022, letter as the Tritium Pry Bar. The NRC's determination of willfulness was not based on a finding that Cammenga deliberately intended to violate NRC requirements, but rather on Cammenga's careless disregard in failing to pursue necessary actions to ensure Cammenga's compliance. Willful violations are of significant concern to the NRC because the NRC's regulatory programs rely upon the integrity of entities, applicants, and licensees to comply with NRC regulations and requirements.

For both violations identified in the March 17, 2022, letter, the NRC considered whether Cammenga had taken corrective actions to restore and maintain compliance. The insufficient information regarding Cammenga's corrective actions warranted a response by the licensee to the final action including providing a detailed description of its corrective actions."

In the March 17, 2022, letter, the NRC offered Cammenga the choice to: (1) respond in writing to the apparent violations addressed in the NRC's inspection report within 30 days of the date of the letter; (2) request a Pre-decisional Enforcement Conference (PEC); or (3) request ADR mediation. Cammenga requested ADR.

On June 28, 2022, Cammenga and the NRC met in an ADR session mediated by a professional mediator, arranged through Cornell University's Institute on Conflict Resolution. The ADR process is one in which a neutral mediator, with no decision-making authority, assists the parties in reaching an agreement on resolving any

differences regarding the dispute. This Confirmatory Order is issued pursuant to the agreement reached during the ADR process.

III

As a result of an ADR mediation session held on June 28, 2022, NRC and Cammenga reached a preliminary agreement. The elements of the agreement, as signed by both parties on June 28, 2022, consisted of the following:

1. Cammenga shall issue a company policy statement to its employees regarding the importance of regulatory compliance.
 - a. The Policy Statement regarding Regulatory Compliance shall provide Cammenga management's position on (1) the importance of ensuring full understanding of the regulatory and license requirements, (2) the ethics of complying with regulatory requirements, (3) the awareness that willful violations are unacceptable, pursuant to the requirements of 10 CFR 30.9 and 30.10, (4) that there are potential criminal sanctions that the Department of Justice may take against individuals for deliberate misconduct, and (5) the need to ensure the primacy of regulatory compliance over competing goals.
 - b. **Within 60 days** of the date of the Confirmatory Order, Cammenga shall create and provide copies of the company policy statement to all employees.
 - c. **Within 60 days** of the date of the Confirmatory Order, Cammenga shall provide a copy of company policy statement to the NRC.

- d. Cammenga shall maintain copies of the company policy statement for NRC inspection.
- 2. Cammenga shall issue a letter to its current resellers articulating the existence of regulatory requirements, the importance of distributing only products that are authorized, and the importance of asking their suppliers to confirm that the product is properly authorized.
 - a. **Within 60 days** of the date of the Confirmatory Order, Cammenga shall issue the letter to current resellers.
 - b. **Within 60 days** of the date of the Confirmatory Order, Cammenga shall provide a copy of the letter to the NRC.
 - c. Cammenga shall maintain copies of the letter for NRC inspection.
- 3. Cammenga shall conduct initial and annual refresher training for all engineering and management personnel that are responsible for ensuring compliance with all active NRC Exempt Distribution Licenses and Sealed Source and Device Certificates. The training shall consist of reviewing all active NRC Exempt Distribution Licenses and Sealed Source and Device Certificates.
 - a. Cammenga shall maintain documentation for training completed. The training documentation shall include a summary of the contents of the training and the individuals completing the training. The training documentation shall be maintained for 5 years. The training can be a read-and-sign.
 - b. **Within 60 days** of the date of the Confirmatory Order, Cammenga shall conduct the initial training for all current individuals engaged in licensed activities.
 - c. For individuals not currently engaged in the above activities, Cammenga shall conduct initial training prior to engagement in relevant activities.

- d. **By December 31 of each calendar year**, Cammenga shall conduct annual refresher training for all individuals engaged in relevant activities.
 - e. Cammenga shall maintain copies of the training documentation for NRC inspection.
- 4. **Within 90 days** of the date of the CO, Cammenga shall create and maintain and implement written procedures to ensure that only products approved on the distribution license shall be distributed. The procedures will be available for NRC inspection.
- 5. **Within 90 days** of the date of the CO, Cammenga shall create and maintain written procedures for a process for new or changed designs to ensure the design either (1) fits within what is currently authorized, or (2) an amendment is submitted and approved by the NRC prior to distribution. The process will include a step to assess if it is appropriate to request a pre-application meeting with NRC. The procedures will be available for NRC inspection.
- 6. Cammenga commits to cease distribution of the Tritium Pry Bar and Tritium Glow Fob (Cammenga will provide the product number for these two models for the CO), until such time as Cammenga receives written confirmation from NRC that the model is approved.
- 7. **Within 180 days** of the date of the CO, Cammenga will perform an audit of all current models in inventory or production to confirm products are authorized for distribution.
 - a. Cammenga will not distribute any models not confirmed authorized for distribution.

- b. Cammenga will document the review. The documentation will include the following: list of models reviewed, determination whether the model is authorized for distribution, and if authorized, the number of the associated SSD and drawing number.
 - c. The documentation will be available for NRC inspection and will be maintained for three years.
- 8. Cammenga will perform an annual assessment of program and compliance for NRC License No. 21-26460-03E. The review will specifically include: review for implementation of appropriate procedures, verification that training was completed and documented as per the ADR CO, and that all new/changed products were reviewed under the new/change product process. Cammenga will maintain documentation of the review. The documentation will be available for NRC inspection, and will be maintained for at least three years.
 - a. **By December 31 of each calendar year**, Cammenga shall conduct an annual assessment of program and compliance.
- 9. Cammenga shall pay a civil penalty of \$5000.
 - a. **Within 30 days** of the date of the Confirmatory Order, Cammenga shall pay a civil penalty of \$5000. Cammenga shall pay the civil penalty in accordance with NUREG/BR-0254, "Payment Methods".
 - b. **Within 45 days** of the date of the Confirmatory Order, Cammenga shall submit to the NRC, a statement indicating when and by what method payment was made.

On September 21, 2022, Cammenga consented to issuing this Confirmatory Order with the commitments, as described in Section V below. Cammenga further

agreed that this Confirmatory Order is to be effective upon issuance of the Confirmatory Order and that it has waived its right to a hearing.

IV

Since the licensee has agreed to take additional actions to address NRC concerns, as set forth in Section III above, the NRC has concluded that its concerns can be resolved through issuance of this Confirmatory Order.

I find that Cammenga's commitments as set forth in Section V are acceptable and necessary and conclude that with these commitments the public health and safety are reasonably assured. In view of the foregoing, I have determined that public health and safety require that Cammenga's commitments be confirmed by this Confirmatory Order. Based on the above and Cammenga's consent, this Confirmatory Order is effective upon issuance of the Confirmatory Order.

V

Accordingly, pursuant to Sections 81, 161b, 161i, 161o, 182 and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.202 and 10 CFR Part 30, IT IS HEREBY ORDERED THAT LICENSE NO. 21-26460-03E IS MODIFIED AS FOLLOWS:

1. Cammenga shall issue a company policy statement to its employees regarding the importance of regulatory compliance.
 - a. The Policy Statement regarding Regulatory Compliance shall provide Cammenga management's position on (1) the importance of ensuring full

understanding of the regulatory and license requirements, (2) the ethics of complying with regulatory requirements, (3) that willful violations are unacceptable, pursuant to the requirements of 10 CFR 30.9 and 30.10, (4) that there are potential criminal sanctions that the Department of Justice may take against individuals for deliberate misconduct, and (5) the need to ensure the primacy of regulatory compliance over competing goals.

- b. **Within 60 days** of the date of the Confirmatory Order, Cammenga shall create and provide copies of the company policy statement to all employees.
 - c. **Within 60 days** of the date of the Confirmatory Order, Cammenga shall create and provide copies of the company policy statement to the NRC.
 - d. Cammenga shall maintain copies of the company policy statement for NRC inspection.
- 2. Cammenga shall issue a letter to its current resellers articulating the existence of regulatory requirements, the importance of distributing only products that are authorized, and the importance of asking their suppliers to confirm that the product is properly authorized.
 - a. **Within 60 days** of the date of the Confirmatory Order, Cammenga shall issue the letter to current resellers.
 - b. **Within 60 days** of the date of the Confirmatory Order, Cammenga shall provide a copy of the letter to the NRC.
 - c. Cammenga shall maintain copies of the letter for NRC inspection.
- 3. Cammenga shall conduct initial and annual refresher training for all engineering and management personnel that are responsible for ensuring compliance with any active NRC Exempt Distribution Licenses and Sealed Source and Device

Certificates. The training shall consist of reviewing all active NRC Exempt Distribution Licenses and Sealed Source and Device Certificates.

- a. Cammenga shall maintain documentation for training completed. The training documentation shall include a summary of the contents of the training and the individuals completing the training. The training documentation shall be maintained for five years. The training can be a read-and-sign.
 - b. **Within 60 days** of the date of the Confirmatory Order, Cammenga shall conduct the initial training for all current individuals engaged in licensed activities.
 - c. For individuals not currently engaged in licensed activities, Cammenga shall conduct initial training prior to engagement in such activities.
 - d. **By December 31 of each calendar year**, Cammenga shall conduct annual refresher training for all individuals engaged in such activities.
 - e. Cammenga shall maintain copies of the training documentation for NRC inspection.
4. **Within 90 days** of the date of the Confirmatory Order, Cammenga shall create, maintain, and implement written procedures to ensure that only products approved on the distribution license shall be distributed. The procedures shall be available for NRC inspection.
5. **Within 90 days** of the date of the Confirmatory Order, Cammenga shall create, maintain, and implement written procedures for a process for new or changed designs to ensure that either (1) the design fits within what is currently authorized, or (2) a license amendment is submitted and approved by the NRC prior to distribution. The process shall include a step to assess whether it is

appropriate to request a pre-application meeting with NRC. The procedures shall be available for NRC inspection.

6. Cammenga shall cease distribution of the Tritium Pry Bar and Tritium Glow Fob , until such time as Cammenga receives written confirmation from NRC that the models are approved.
7. **Within 180 days** of the date of the Confirmatory Order, Cammenga shall perform an audit of all current models in inventory or production to confirm the products are authorized for distribution.
 - a. Cammenga shall not distribute any models not confirmed as authorized for distribution.
 - b. Cammenga shall document the audit review. The documentation shall include (1) the list of models reviewed, (2) determination of whether the model is authorized for distribution, and if authorized, (3) the associated SSD number and drawing number.
 - c. The documentation shall be available for NRC inspection, and Cammenga shall maintain the documentation for three years.
8. Cammenga shall perform an annual assessment of program and compliance for NRC License No. 21-26460-03E. The assessment shall specifically include: (1) review for implementation of appropriate procedures, (2) verification that training was completed and documented as per the ADR Confirmatory Order, and (3) verification that all new/changed products have been reviewed under the new/change product process established in accordance with paragraph 5 above. Cammenga shall maintain documentation of the assessment. The documentation shall be available for NRC inspection, and Cammenga shall maintain the documentation for at least three years.

- a. **By December 31 of each calendar year**, Cammenga shall conduct an annual assessment of program and compliance.

9. Cammenga shall pay a civil penalty of \$5000.

- a. **Within 30 days** of the date of the Confirmatory Order, Cammenga shall pay a civil penalty of \$5000. Cammenga shall pay the civil penalty through one of the following methods:

- i. Submit the payment with the enclosed invoice to this Order (EA-21-157) to the following address:

Office of the Chief Financial Officer

U.S. Nuclear Regulatory Commission P.O. Box 979051

St. Louis, MO 63197

OR

- ii. Submit the payment in accordance with NUREG/BR-0254, "Payment Methods".

- b. **Within 45 days** of the date of the Confirmatory Order, Cammenga shall submit to the NRC, a written statement indicating when and by what method payment was made. to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, One white Flint North, 11555 Rockville Pike, Rockville, MD 20852-2738.

The NRC considers the corrective actions discussed above to be appropriately prompt and comprehensive.

The NRC agrees not to pursue any further enforcement action in connection with the NRC's March 17, 2022, letter to Cammenga.

The Confirmatory Order shall constitute escalated enforcement action.

This agreement is binding upon successors and assigns of NRC License No. 21-26460-03E.

In the event of the transfer of the possession and/or distribution licenses of Cammenga to another entity, the terms and conditions set forth hereunder shall continue to apply to the new entity and accordingly survive any transfer of ownership or license.

Unless otherwise specified, all dates are from the date of issuance of the Confirmatory Order.

Unless otherwise specified, all documents required to be submitted to the NRC shall be sent to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852-2738, with a copy to the Director, Materials Safety, Security, State, and Tribal Programs, Two White Flint North, 11545 Rockville Pike, Rockville, MD 20852-2738. Cammenga will also endeavor to provide courtesy electronic copies to the above individuals.

The Director, Office of Enforcement, may, in writing, relax or rescind any of the above conditions upon demonstration by the Licensee of good cause.

VI

In accordance with 10 CFR 2.202 and 10 CFR 2.309, any person adversely affected by this Confirmatory Order, other than Cammenga, may request a hearing within thirty (30) calendar days of the date of issuance of this Confirmatory Order. Where good cause is shown, consideration will be given to extending the time to request a hearing. A request for extension of time must be made in writing to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and include a statement of good cause for the extension.

All documents filed in NRC adjudicatory proceedings including documents filed by an interested State, local governmental body, federally recognized Indian Tribes, or designated agency thereof that requests to participate under 10 CFR 2.315(c), must be filed in accordance with 10 CFR 2.302. The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases, to mail copies on electronic storage media, unless an exemption permitting an alternative filing method, as further discussed, is granted. Detailed guidance on electronic submissions is located in the “Guidance for Electronic Submissions to the NRC” (ADAMS Accession No. ML13031A056) and on the NRC’s public website at <https://www.nrc.gov/site-help/e-submittals.html>.

To comply with the procedural requirements of E-Filing, at least 10 days prior to the filing deadline, the participant should contact the Office of the Secretary by email at Hearing.Docket@nrc.gov, or by telephone at 301-415-1677, to (1) request a digital identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign submissions and access the E-Filing system for any

proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a petition or other adjudicatory document (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on the NRC's public website at <https://www.nrc.gov/site-help/e-submittals/getting-started.html>. After a digital ID certificate is obtained and a docket created, the participant must submit adjudicatory documents in Portable Document Format. Guidance on submissions is available on the NRC's public website at <https://www.nrc.gov/site-help/electronic-sub-ref-mat.html>. A filing is considered complete at the time the document is submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. ET on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an email confirming receipt of the document. The E-Filing system also distributes an email that provides access to the document to the NRC's Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the document on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before adjudicatory documents are filed to obtain access to the documents via the E-Filing system.

A person filing electronically using the NRC's adjudicatory E-Filing system may seek assistance by contacting the NRC's Electronic Filing Help Desk through the "Contact Us" link located on the NRC's public website at <https://www.nrc.gov/site-help/e-submittals.html>, by email to MSHD.Resource@nrc.gov, or by a toll-free call at

1-866-672-7640. The NRC Electronic Filing Help Desk is available between 9:00 a.m. and 6:00 p.m., ET, Monday through Friday, except Federal holidays.

Participants who believe that they have good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing stating why there is good cause for not filing electronically and requesting authorization to continue to submit documents in paper format. Such filings must be submitted in accordance with 10 CFR 2.302(b)-(d). Participants filing adjudicatory documents in this manner are responsible for serving their documents on all other participants. Participants granted an exemption under 10 CFR 2.302(g)(2) must still meet the electronic formatting requirement in 10 CFR 2.302(g)(1), unless the participant also seeks and is granted an exemption from 10 CFR 2.302(g)(1).

Documents submitted in adjudicatory proceedings will appear in the NRC's electronic hearing docket, which is publicly available at <https://adams.nrc.gov/ehd>, unless excluded pursuant to an order of the presiding officer. If you do not have an NRC-issued digital ID certificate as previously described, click "cancel" when the link requests certificates and you will be automatically directed to the NRC's electronic hearing dockets where you will be able to access any publicly available documents in a particular hearing docket. Participants are requested not to include personal privacy information such as social security numbers, home addresses, or personal phone numbers in their filings unless an NRC regulation or other law requires submission of such information. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants should not include copyrighted materials in their submission.

If a person other than the licensee requests a hearing, that person shall set forth with particularity the manner in which his interest is adversely affected by this Confirmatory Order and shall address the criteria set forth in 10 CFR 2.309(d) and (f).

If a hearing is requested by a person whose interest is adversely affected, the Commission will issue a separate Order designating the time and place of any hearings, as appropriate. If a hearing is held, the issue to be considered at such hearing shall be whether this Confirmatory Order should be sustained.

In the absence of any request for hearing, or written approval of an extension of time in which to request a hearing, the provisions specified in Section V above shall be effective and final 30 days after issuance of the Confirmatory Order without further order or proceedings. If an extension of time for requesting a hearing has been approved, the provisions specified in Section V shall be final when the extension expires if a hearing request has not been received.

FOR THE NUCLEAR REGULATORY
COMMISSION

/RA/

Mark D. Lombard, Director
Office of Enforcement

Dated this 6th day of October 2022

